REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejections of the present application are respectfully requested in view of the amendments to the claims and remarks presented herewith, which place the application into condition for allowance.

Status of the Claims and Formal Matters

With the amendments here, claims 4-11, and claims 16 - 156 stand cancelled. Claims 1, 2, 3, 12-15 and 157 are pending. Independent claim 1 has been amended to recite a total daily dose of 400 mg once daily of SAHA or pharmaceutically acceptable salt or hydrate thereof. This amendment is supported by the specification as filed. See p. 65, lines 5-15. The claims that depend therefrom have been amended to change claim dependency and clarify the antecedent basis of claims 14 and 15. No new matter has been introduced by these amendments.

Rejections under 112, 2nd paragraph.

Claim 6 and claim 36 have been rejected under 35 U.S.C.§ 112, second paragraph because of the reference to "Burkitt's type leukemia" in parentheses. Claims 6 and 36, have been cancelled -- thus Applicants believe that the 35 U.S.C.§ 112, second paragraph rejection is moot and should be withdrawn.

Rejections under 35 U.S.C §103(a)

Claims 1-10, 12-28, 30-36, 38-43, 45-50, 52-57, 59-63, 95-96, 98, 100, 102-104, 106, 108, 110-112, 114, 116, 118-120, 122, 124, 126-128, 130, 132, 134-136, 138, 140, 142, 157, 160, 163, 166, 169, 172, 175 and 178 stand rejected under 35 U.S.C §103(a) as allegedly obvious over DiMartino et al (US Patent No. 6,905,669, "DiMartino") in view of Richon et al (US 2003/0235588; "Richon"). The Office Action further contends that "when taken together with Richon et al evidence is provided that the instantly claimed oral doses of HDAC inhibitors, including SAHA were known in the art"(Office Action, page 6). Applicants respectfully traverse.

The Examiner is thanked for acknowledging Applicants prior arguments over DiMartino (Office Action page 6). As the Examiner concedes, DiMartino does not disclose the instantly claimed 400 mg oral dose of SAHA and instant dosing schedule of once daily for treatment of leukemia, and thus does not teach or suggest all of the claim limitations.

Since DeMartino does not provide the instantly claimed dosage, it is totally defective. As discussed below, Richon is not prior art -- thus the combination must fail.

Richon is not prior art under 35 U.S.C §103. Under §103(c), subject-matter that was developed by another person shall not preclude patentability where the subject-matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. Subject-matter developed by another person and a claimed invention are deemed to have been owned by the same person or subject to an obligation of assignment to the same person if (A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; (B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. Cooperative Research and Technology Enhancement Act of 2004, 118 Stat. 3596.

The subject matter of the instant application and Richon was made, owned by, or subject to an obligation of assignment to the Memorial Sloan-Kettering Cancer Center, at the time the present invention was made. Thus, according to the MPEP §706.02 (1) (2) (I and II) and the provisions of 35 U.S.C. §103 (c), the common ownership of the claimed inventions precludes a rejection under 35 U.S.C. §103 in view of Richon.

Claims 97, 99, 101, 105, 107, 109, 113, 115, 117, 121, 123, 125, 129, 131, 133, 137, 139, 141, 158-159, 161-162, 164-165, 167-168, 170-171, 173-174 and 176-177 are being rejected under 35 USC § 103(a) as being allegedly obvious over DiMartino and Richon in further view of Kelly et al. (Proc. American Society of Clinical Oncology, 2001, 20:87a, Abstract No.344, "Kelly"). This rejection is moot as all the rejected claims have been cancelled (with the

exception of dependent claim 157 which is patentable for the reasons discussed elsewhere in this paper).

Claims 1, 7-8, 12-26, 43, 45-49, 119-120, 122, 124, 126, 157 and 169, are rejected under 35 U.S.C.§103(a) as being allegedly obvious over Richon in view of Nilsson et al (Blood, 2000, vol.95, pages 1420-1426; "Nilsson"). The Examiner contends that Richon allegedly discloses the instantly claimed HDAC inhibitor as well as oral formulations and Nilsson allegedly provides the nexus and motivation to use the methods disclosed in Richon to treat leukemia. Applicants traverse. All rejected claims with the exception of claims 1, 12 - 15 and 157 have been cancelled.

As discussed above, Richon is not available as prior art and thus can not be used to make the instant obviousness rejection. Nilsson does not render the remaining pending claims obvious. Nilsson is an *in vitro* study that relates to the signaling cascade activated by TRX stimulation of B-cells. Specifically, the study found that TRX stimulated autocrine TNF-alpha release in a dose-dependent manner and thus rescued B-CLL cells from spontaneous apoptosis. Nothing in Nilsson would cause the ordinarily skilled scientist to extrapolate the claimed dose and dosing schedule for treatment of patients with leukemia. The Examiner concedes that Nilsson does not disclose the specific claimed dosages and administration schedules. The claims are patentable are Nilsson and the rejection should be withdrawn.

Finally, claims 121, 123, 125, and 164-168 are rejected under 35 U.S.C. §103(a) as being unpatentable over Richon and Nilsson in further view of Kelly. The rejection is moot as all rejected claims have been cancelled.

CONCLUSION

Favorable action on the merits is respectfully requested. If any discussion regarding this Amendment is desired, the Examiner is respectfully urged to contact the undersigned at the number given below, and is assured of full cooperation in progressing the application to allowance.

Applicants believe that no additional fees are due with the filing of this Amendment. However, if any additional fees are required or if any funds are due, the USPTO is authorized to charge or credit Deposit Account Number: **50-0311**, Customer Number: **35437**, Reference Number: **24852-513**.

Respectfully submitted,

Dated: June 29, 2007

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